REMARKS

I. Overview

Claims 1-21 are pending in the present application. Claims 12-21 have been withdrawn. Claims 1-11 are being examined. Claim 4 has been amended to correct typographical error without the addition of any new matter. Claim 1 has been amended and new claim 22 has been added. No new matter has been added, as support for the claim amendments and new claim can be found, for example, at least in the originally filed specification at page 10, lines 10-20 and originally filed claim 1.

The present response is an earnest effort to place all pending claims in proper form for immediate allowance. Reconsideration and passage to issuance is therefore respectfully requested.

II. Claim Objection

Claim 4 stands objected to because of the following informalities: "non-infectioe" seems to be misspelled. Claim 4 has been amended to show the correct spelling and this objection should be withdrawn.

III. Claim Rejections Under 35 U.S.C. § 112

The Examiner presents new rejections under 35 U.S.C. § 112 not previously presented. Applicants respectfully traverse each and every § 112 rejection made by the Examiner hereunder.

A. Claims 1-11 stand rejected under 35 U.S.C. § 112, first paragraph, because the Examiner states that the specification, while being enabling for a method of detecting isoforms of SAA protein or mRNA encoding the protein having SEQ ID NO:1, it does not reasonably

provide enablement for any other isoform of SAA protein. The Examiner further states the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Applicants respectfully traverse the Examiner's rejection.

Applicants have clearly set forth a novel method for detecting an inflammatory response in a breast of a lactating mammal supported by an enabling disclosure as required under 35 U.S.C. § 112, first paragraph. SEQ ID NO:1 for bovine SAA is disclosed by Applicants. However, Applicants clearly set forth in its specification that other species are included within the metes and bounds of the invention. (page 4, lines 23-27; page 9, lines 29-32). Applicants define the term "immunologically specific" as referring to antibodies binding one or more epitopes of a protein of interest. (page 6, lines 32-34). Notably, the immunologically specific antibodies "do not substantially recognize and bind other molecules in a sample." (page 7, lines 1-3). Applicants continue its enabling disclosure, for example at least at, page 10, lines 31-35 identifying that antibodies are immunologically specific for "one or more isoforms of SAA." Accordingly, it is within Applicants' claimed invention, as described in the specification, not to exclude any SAA isoforms.

Moreover, the Examiner is directed to, for example, page 11, lines 12-14 wherein yet another preferred embodiment discloses antibodies prepared to react with a "variety of SAA isoforms." In fact, page 11, lines 12-14 further explains that "these antibodies, raised against human SAA, also react with a variety of SAA isoforms from other species, including bovine SAA." Still further, the assays disclosed by Applicants in the specification are capable of detecting this same range of SAA isoforms disclosed by Applicants, as would be easily discernable by a person of ordinary skill in the art. Such skilled artisan would clearly be enabled

by Applicants' specification to detect SAA in milk from various other species, where it is present, given that other species are included within the specification.

For at least these reasons, the bovine SAA of SEQ ID NO:1 is not the only enabled claim element as the Examiner alleges. Rather, a much greater variety of SAA isoforms are set forth in Applicants' enabled disclosure, as required pursuant to 35 U.S.C. § 112, first paragraph. Accordingly, Applicants have provided a specification describing for skilled artisans how to make and used the claimed invention. *CFMT, Inc. v. Yieldup Int'l Corp.*, 349 F.3d 1333, 68 USPQ2d 1940 (Fed. Cir. 2003). Moreover, Applicants examples, methods, assays and preferred embodiments disclosed within the specification provide for an enabling specification which does not require undue experimentation for a skilled artisan to make and use the claimed invention. *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). Accordingly, Applicants respectfully request the Examiner withdrawn the § 112 rejection and place the claims in condition for allowance.

B. Claims 1-11 stand rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for SAA isoforms for diagnosing mastitis, does not reasonably provide enablement for all SAA isoforms or for all inflammatory responses. The Examiner states the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Applicants respectfully traverse the Examiner's rejection.

Applicants have again clearly set forth a novel method for detecting an inflammatory response in a breast of a lactating mammal that is supported by an enabling disclosure as required under 35 U.S.C. § 112, first paragraph, for both a variety of inflammatory responses as well as isoforms of SAA, beyond merely SEQ ID NO:1 for bovine SAA. Respectfully, the Examiner is

directed to the language of claim 1 to determine whether a skilled artisan may make and use the invention commensurate in scope with these claims. Here, Applicants claim (claim 1) a "method for detecting an inflammatory response in a breast of a lactating mammal, comprising: obtaining a milk sample from the breast of a mammal; measuring the presence or amount of a Serum Amyloid A (SAA) protein or mRNA encoding the protein from the sample; and correlating the amount of the SAA protein or mRNA present in the sample with the inflammatory response." (emphasis added).

The claim language is not directed to any and all inflammatory responses; rather as the claim language clearly sets forth, the inflammatory responses are inherently inclusive of only those inflammatory responses in a breast of a lactating animal and measurable according to the presence and amount of SAA in its milk. This is further supported in the originally-filed specification, for example at page 4, lines 24-25 wherein the SAA is "one or more inflammatory-responsive isoforms of SAA." (emphasis added). Such requirement for "inflammation responsive" SAAs precludes reading the claims to include each and every inflammatory response; rather only the inflammatory-responsive isoforms of SAA are included within the scope of the claims. Notably, such inflammatory-responsive isoforms of SAA may include both infectious and non-infectious inflammation of the udder. (*See, e.g.*, page 3, lines 16-20; page 4, lines 19-22).

Such support in the specification is commensurate in scope with the claimed invention, as set forth in the independent claim. Accordingly, Applicants are not claiming every possible type of inflammatory response. Rather, only inflammatory responses in the breast of a lactating mammal which results in one or more inflammatory-responsive isoforms of SAA are included within the claimed language and clearly supported and enabled by the specification as set forth

herein by Applicants. As a result, Applicants respectfully request the Examiner withdrawn the § 112 rejection and place the claims in condition for allowance.

C. Claims 5-6 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Examiner states the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The Examiner further states the specification fails to describe the one or more inflammatory responsive isoforms of SAA that relate to other inflammatory responses and as mentioned above, inflammatory response would encompass not only mastitis but other conditions such as allergic response, inflammatory breast cancer, etc. Applicants respectfully traverse the Examiner's rejection.

The written description requirement is satisfied when the specification contains "a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention." 35 U.S.C. § 112, first paragraph. The written description clearly states that "Applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention" which is for purposes of the 'written description' inquiry, whatever is claimed. *See Vas-Cath Incorporated v. Mahurkar*, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). Accordingly, the specification must "clearly allow persons of ordinary skill in the art to recognize that (he or she) invented what is claimed." *Id.* at 1116.

As set forth above for the Examiner, Applicants' specification contains support for each and every claim limitation, resulting in a specification that is both enabled and contains a written description commensurate with the claims of the present invention. Claims 5 and 6 of the application are directed to "one or more inflammation-responsive isoforms of SAA" and to SAA comprising "an amino acid sequence selected from the group consisting of SEQ ID NOS: 1-15." Applicants' specification, as originally filed, describes SAA as acute phase proteins present in response to inflammation related to tissue injury or infection, including other conditions besides mastitis, including for example, mechanical injury, ganulomatous disease, fibrocystic disease and cancer. (page 7, lines 18-22; page 8, lines 12-20). Further various types of injury are measurable by the various inflammatory-responsive isoforms of SAA, including SEQ ID NOS: 1-15. (page 10, lines 5-20). At least these examples of adequate written description contained within Applicants' specification demonstrate Applicants were in possession of the claimed invention. *See, e.g., Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 68 (1998).

Accordingly, Applicants specification satisfies the written description requirement as it clearly sets forth the technology to be protected, and demonstrates that Applicants were in possession of the claimed invention through the inclusion of the patent specification describing the claimed invention in sufficient detail for a skilled artisan. *See, e.g., Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 66 USPQ2d 1429 (Fed. Cir. 2003). Therefore, Applicants respectfully request the Examiner withdrawn the § 112 rejection and place the claims in condition for allowance.

IV. Double Patenting

Claims 1, 5, 6-9 stand rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 5 and 16 of U.S. Patent No. 6,509,444 in view of Hirai *et al.* (U.S. Patent No. 5,216,127). The Examiner states that U.S. Patent No. 6,509,444 teaches a method of separating or isolating an SAA having SEQ ID NO:1, from a colostrum sample of a mammal. However, the Examiner acknowledges that U.S. Patent No. 6,509,444 fails to teach a step of measuring the presence or amount of said SAA protein and performing an ELISA assay. However, the Examiner states that Hirai *et al.* teach performing an ELISA assay to detect SAA protein in any fluid component originated in a living body. (*See* Hirai *et al.* col. 3, lines 17-20; col. 19, line 50; abstract).

Accordingly, the Examiner states it would have been obvious to one of ordinary skills in the art to detect or measure the presence or amount of SAA protein in a sample using ELISA assay method as taught by Hirai *et al.* as a sequential step in the method of U.S. Patent No. 6,509,444 to detect the presence or amount of SAA since a detection step must be performed in order to confirm that there is any SAA being separated in the method of U.S. Patent No. 6,509,444.

Applicants respectfully continue to traverse the Examiner's nonstatutory obviousness-type double patenting rejection in accordance with those arguments previously presented and those newly presented herein. The claims of U.S. Patent No. 6,509,444 and Hirai *et al.* do not result in either anticipation or an obvious variation of such claims as required for patentably indistinct claims. *See, e.g., In re Berg*, 140 USPQ 1428, 46 USPQ2d 1226 (Fed. Cir. 1998). Furthermore, Applicants point out that such analysis is made in light of the "conflicting claims – a claim in the patent compared to a claim in the application." MPEP 804. It is clearly set forth that the

disclosure of the patent is not be used as prior art as this is a claim by claim comparison. *General Foods Corp. v. Studiengesellschaft Kohle* mbH, 972 F.2d 1272, 1279, 33 USPQ2d 1839, 1846 (Fed. Cir. 1992). Herein, Applicants present additional evidence to demonstrate the claims of the present invention are patentably distinct from the claims of U.S. Patent No. 6,509,444 and Hirai *et al.* requiring withdrawal of the Examiner's nonstatutory obviousness-type double patenting rejection.

U.S. Patent No. 6,509,444 and Hirai *et al.* do not anticipate nor render obvious Applicants' claims 1, 5 and 6-9 directed to a diagnostic application to assaying and utilize immunologically specific antibodies of SAA isoforms. As amended, claim 1 recites: "A method for detecting an inflammatory response in a breast of a lactating mammal, comprising: obtaining a milk sample from the breast of a mammal; measuring the presence or amount of a Serum Amyloid A (SAA) protein or mRNA encoding the protein from the sample; and correlating the amount of the SAA protein or mRNA present in the sample with the inflammatory response." Further, newly presented claim 22 recites: "A method for detecting an inflammatory response in a breast of a lactating mammal, comprising: obtaining a milk sample from the breast of a mammal; measuring the presence or amount of a Serum Amyloid A (SAA) protein or mRNA encoding the protein from the sample, wherein the SAA is an amino acid sequence set forth as SEQ ID NO:1; and correlating the amount of the SAA protein or mRNA present in the sample with the inflammatory response."

In contrast to the claims of the present invention, U.S. Patent No. 6,509,444 merely discloses a novel isoform of SAA occurring in elevated levels in colostrum, whereas the claims of the present invention cover the diagnostic applications of SAA in milk as a result of inflammation. Moreover, the present claims, as exemplified in the amended claims 1 and 22, are

directed to the method steps including obtaining a milk sample, measuring the amount of SAA protein or mRNA and finally correlating the SAA with an inflammatory response in the mammal. Accordingly, the claims of the present invention are directed to assaying for the expressed protein or the mRNA encoding the protein and establishing a correlation to an inflammatory response. The claims of U.S. Patent No. 6,509,444 fail to disclose the steps of measuring the SAA and correlating the SAA with an inflammatory response. The claim language of U.S. Patent No. 6,509,444 merely discloses the separation of the SAA, a separate and distinct process from measuring an amount of SAA. Moreover, the claims of U.S. Patent No. 6,509,444 fail to disclose any relationship between the SAA obtained from a sample of colostrum with any condition in the mammal, including an inflammatory response. As a result, the claim to claim comparison, as required pursuant to MPEP 804 for the double-patenting rejection, illustrates that U.S. Patent No. 6,509,444 does not result in either anticipation or an obviousness rejection required for patentably indistinct claims. *See, e.g., In re Berg*, 140 USPQ 1428, 46 USPQ2d 1226 (Fed. Cir. 1998).

Applicants further traverse the Examiner's statement that Hirai *et al.* teaches performing an ELISA assay to detect SAA protein in any fluid component originated in a living body (*see* col. 3, lines 17-20; col. 19, line 50; abstract). In fact, Hirai *et al.* is directed to the ability of an absorbent to remove SAA from a biologic fluid; in fact the samples of Hirai *et al.* were in fact pre-treated with an absorbent prior to examining the supernatant to determine the amount of SAA remaining. Accordingly, the Hirai *et al.* assay was used merely to demonstrate the level of effectiveness of the absorbent and the reference does not disclose the use of ELISA for monitoring inflammation (*i.e.*, increasing SAA) such that the application of analyzing SAA in milk, as disclosed in Applicants' invention, is not an obvious or anticipated variation. As

referenced herein, the assay was not used for such a purpose as the Examiner sets forth. Rather, the assay disclosed by Hirai *et al.* is merely a tool to demonstrate the effectiveness of the absorbent by analyzing the residual SAA in a supernatant. Still further, the assay disclosed by Hirai *et al.* for the detection of SAA does not provide an enabling disclosure under 35 U.S.C. § 112, such that a skilled artisan would be unable to generate a proper and reliable test.

Moreover, Hirai *et al.* fails to make any reference to SAA in milk nor mastitis or any inflammatory condition of an udder. This is demonstrated by the lack of any reference to inflammation, mastitis or any other related condition or the use of monitoring such conditions that would be applicable to Applicants' claims 1, 5 and 6-9. Again, the Examiner's cited references fail to disclose the present claims' elements of: (1) obtaining a milk sample; (2) measuring the amount of SAA protein or mRNA; and (3) correlating the SAA with an inflammatory response in the mammal. This is further demonstration that the claims of both patents cited by the Examiner fail to result in patentably indistinct claims in order to justify the Examiner's nonstatutory obviousness-type double patenting rejection.

As a result, the claims of the present invention are patentably distinct from those of U.S. Patent No. 6,509,444 and Hirai *et al.* as the claims of the present invention are directed to the novel diagnostic methods of measuring SAA protein or mRNA in milk and correlating the amount of SAA with an inflammatory response. In fact, despite research and references such as those cited by the Examiner herein, no skilled artisan has achieved or even disclosed the possibility of a method for assaying and utilizing immunologically specific antibodies for novel isoforms of SAA for the correlation of SAA with inflammatory responses, and would not been able to accomplish such absent the disclosure presented in the present invention by Applicants. For at least these reasons, the invention of the claimed patent is patentably distinct from U.S.

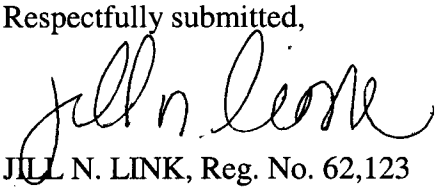
Patent No. 6,509,444 in view of Hirai *et al.*, according to MPEP 804. Applicants respectfully request the Examiner withdraw the nonstatutory obviousness-type double patenting rejection and place the claims in condition for immediate allowance.

V. Conclusion

Please charge Deposit Account No. 26-0084 the amount of $272.00 for one new claim over 20 ($52) and one new claim over 3 ($220).

No fees or extensions of time are believed to be due in connection with this amendment; however, consider this a request for any extension inadvertently omitted, and charge any additional fees to Deposit Account No. 26-0084.

Respectfully submitted,



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